

## **REMARKS**

This paper is in response to the Office Action dated September 18, 2008. Applicants have amended the application as set forth above. Specifically, Claims 1, 6, 10, and 12 have been amended. Claims 7-9 have been cancelled. Upon the entry of the amendments, Claims 1-6 and 10-14 are pending in this application. No new matter is added by the amendments as discussed below. Applicants respectfully request the entry of the amendments and reconsideration of the application in view of the above amendments and the following remarks.

### Claim Objections

Claim 1 is objected to because the Examiner stated that two threads are needed to form a tubular structure. Claim 1 has been amended accordingly.

Claim 6 is objected to because two different thread ends from end of stitches cannot form a ring shape. Claim 6 has been amended to recite a loop, which is not necessarily a circle, thereby correcting the informalities in language of the claim.

### Discussion of Amendment

The amendments to Claims 1 and 10 are supported by Applicant's disclosure, for example, in paragraphs [0073] and [0074].

The amendment to Claim 6 is supported by the disclosure, for example, in paragraphs [0069] and [0070] and reference number 2 of Figure 12.

Claim 12 has been amended for grammatical changes.

### Discussion of Rejection of Claims 1-4 and 11-14 Under 35 U.S.C. § 103

The Office Action rejected Claims 1-4 and 10-14 under 35 U.S.C. § 103(a) as being unpatentable over Oi et al. (US Patent No. 6,063,097) in view of Campbell et al. (US Patent No. 6,984,242). In view of the amendments made to Claim 1 this rejection has been overcome.

Claim 1 as amended is directed to a tubular suture reinforcement material for an automatic suturing device, wherein

the tubular suture reinforcement material is formed by stacking two sheet-like materials and sewing together both ends of the two sheet-like materials using two chain

stitches (intralooping stitches), each thread end at each sewing end is suitably extended, and the thread end is passed through an anterior loop continuous to the thread end, thereby preventing the thread from unraveling.

Oi discloses a tubular suture reinforcement material made from a sheet-like material and a single thread. Oi further discloses sewing two sheets of materials to create the tubular structure.

However, Oi does not teach the claimed feature of preventing a stitching from unraveling by extending each sewing end, passing each thread end through an anterior loop continuous to the thread end, thereby preventing the thread (stitching) from unraveling. Oi merely discloses sewing with conventional running stitch technique and knotting the thread end to prevent stitch from unraveling. Therefore, Oi fails to teach the chain stitch feature used in creating the tubular structure and intralooping feature for preventing the stitch from unraveling.

The Office Action asserted that **Campbell** remedies the deficiency of Oi by teaching the chain stitching concept using a single thread. However, Campbell does not teach or suggest unraveling prevention for the stitching. Therefore, Campbell fails to teach the intralooping feature for preventing the stitch from unraveling.

As such, Oi and Campbell in combination would not teach or suggest every feature of Claim 1 to one having ordinary skill in the art. With no additional evidence of teaching these features in the prior art, no *prima facie* obviousness has been established with regard to Claim 1 and its dependent claims 2-6 and 11-14.

#### Discussion of Rejection of Claim 10 Under 35 U.S.C. § 103

The Office Action rejected Claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Oi et al. (US Patent No. 6,063,097) in view of Campbell et al. (US Patent No. 6,984,242). Applicants respectfully disagree with the Office Action, particularly in view of the amendments made in Claim 10 as discussed below.

Claim 10 as amended is directed to a method for manufacturing a tubular suture reinforcement material for an automatic suturing device comprising:

stacking two sheet-like materials,

sewing together both ends of the two sheet-like materials using two chain stitches (intralooping stitches),

suitably extending each thread end at each sewing end, and

passing the thread end through an anterior loop continuous to the thread end.

Some features of amended Claim 10 provide a method for providing the tubular suture reinforcement material as disclosed in Claim 1. Hence, the same reasoning of the above section for asserting features of Claim 1 as unobvious over Oi and Campbell applies to Claim 10.

Therefore, Oi and Campbell in combination or alone do not provide every feature of Claim 10. With no additional evidence of teaching these features in the prior art, no *prima facie* obviousness has been established with regard to Claim 10.

#### Discussion of Rejection of Claims 5 Under 35 U.S.C. § 103

The Office Action rejected Claims 5 under 35 U.S.C. § 103(a) as being unpatentable over Oi et al. (US Patent No. 6,063,097) in view of Campbell and further in view of Dalessandro et al. (US Patent No. 6,273,897). However, since **Dalessandro** adds nothing to address the deficiencies in the *prima facie* sharing of obviousness with regard to Claims 1 as asserted in the above section, claims dependent on Claim 1 including Claim 5 are also unobvious.

#### Discussion of Rejection of Claims 6, 8, and 9 Under 35 U.S.C. § 103

The Office Action rejected Claims 6, 8, and 9 under 35 U.S.C. § 103(a) as being unpatentable over Oi et al. (US Patent No. 6,063,097) in view of Campbell and further in view of Starling et al. (US Patent No. 4,839,215). Claims 8 and 9 have been cancelled and therefore the rejection on Claims 8 and 9 is now moot.

With regard to Claim 6, the Office Action states that Oi and Campbell disclose the tubular suture reinforcement material but lack the ring shape of the sewing ends, and other options of preventing the sutures of unraveling. However, the Office Action asserted that **Starling** remedies the deficiencies of Oi and Campbell. The Office Action asserted on page 7 that Starling teaches the ring shape of sewing ends. Further, the Office Action stated that Starling teaches the ends of the suture material drawn together and surrounded by several turns of another strand of the suture material to prevent the suture from unraveling.

However, in Starling, the turns of the filament are quite different from the structure recited in Claim 6. Starling's turns are made to prevent a "sock structure" containing particles from unraveling. More specifically, as illustrated in Figure 6 of Starling's disclosure, Starling merely binds each end of a "fiber batch" by turning a filament around each end of the fiber batch to bring the fiber batch together at each end. This is done to prevent the ends of the fiber batch from spreading out or becoming loose. Accordingly, the technical concept and teachings of Starling completely differ from the claimed features of the present invention, which is aimed at preventing the suture from unraveling.

Furthermore, Starling merely teaches a large number of apertured particles that are strung on fibers and the threads are strung with ceramic particle beads. This structure completely differs from the suture reinforcement material of the present invention having the ring shape of sewing ends for passing the thread end through an anterior loop (ring shape) continuous to the thread end to prevent unraveling.

Furthermore, it is important to note that for the desired function as a suture prosthetic material, the present invention needs to assure not only prevention of threads from unraveling but also easy removal of thread after the suturing is done using the suturing device. With the turns taught by Starling, it would be difficult to pull out the thread after suturing. As such, one having ordinary skill in the art would not elect to incorporate the turns of Starling into the claimed suture reinforcement material.

Therefore, Oi, Campbell, and Starling in combination do not provide every feature of Claim 6. With no additional evidence of teaching these features in the prior art, no *prima facie* obviousness has been established with regard to Claim 6.

#### Discussion of Rejection of Claims 7 Under 35 U.S.C. § 103

The Office Action rejected Claims 7 under 35 U.S.C. § 103(a) as being unpatentable over Oi et al. (US Patent No. 6,063,097) in view of Campbell and further in view of Tran (US Patent No. 6,652,561). Claim 7 has been cancelled and therefore the rejection is now moot.

Dependent Claims

Although Applicants have not addressed all the issues of the dependent claims, Applicants respectfully submit that Applicants do not necessarily agree with the characterization and assessments of the dependent claims made by the Examiner, and Applicants believe that each claim is patentable on its own merits. Applicants respectfully submit that pursuant to 35 U.S.C. § 112, ¶4, the dependent claims incorporate by reference all the limitations of the claim to which they refer and include their own patentable features, and are therefore in condition for allowance. Therefore, Applicants respectfully request the withdrawal of all claim rejections and prompts allowance of the claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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### CONCLUSION


Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested. If the Examiner has any questions which may be answered by telephone, he or she is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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